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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

ILLUMINA, INC.,

Plaintiff/
Counterclaim-Defendant,

v.

NATERA, INC.,

Defendant/Counterclaim-
Plaintiff.

Case No. 3:18-cv-01662-SI

ILLUMINA, INC.'S MOTION FOR SUMMARY JUDGMENT OF (1) INVALIDITY; AND (2) NON-INFRINGEMENT, OF U.S. PATENT NO. 8,682,592

REDACTED VERSION

Judge: Hon. Susan Y. Illston

Date: May 12, 2020
Time: 10:00 a.m.
Courtroom: 1, 17th Floor

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NOTICE OF MOTION AND MOTION

PLEASE TAKE NOTICE that on May 12, 2020, or as soon thereafter as this motion may be heard, before the Honorable Susan Y. Illston, United States District Court for the Northern District of California, Plaintiff and Counterclaim-Defendant Illumina, Inc. will and hereby does, move this Court pursuant to Fed. R. Civ. P. 56, for an order granting summary judgment that: (1) U.S. Patent No. 8,682,592 is patent ineligible under 35 U.S.C. § 101; and (2) the Illumina Accused Products do not infringe any asserted claim of U.S. Patent No. 8,682,592.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Plaintiff and Counterclaim-Defendant Illumina, Inc. ("Illumina") filed this suit against Natera, Inc. ("Natera") in March 2018 because Natera's Panorama Prenatal Test infringes Illumina's U.S. Patent No. 9,493,831 ("'831 Patent"), and Natera has refused to pay for a license. Illumina's robust patent portfolio, which includes foundational non-invasive prenatal testing ("NIPT") patents in addition to the '831 Patent, has been extensively licensed, but Natera remains a holdout.

After a failed attempt to challenge the validity of the '831 Patent, Natera filed a counterclaim asserting its own U.S. Patent No. 8,682,592 ("'592 Patent")[1], which was patented primarily by individuals with theoretical physics training. According to Natera, the "claimed invention of the '592 patent uniquely addresses, and solves, [the] problems associated with the small amount of genetic material from an embryo or fetus and the inherent noisiness of data extracted from that material." D.I. 61 ¶ 12. In particular, Natera alleges that the '592 Patent describes algorithms to "clean" the "noisy" data for later analysis. *Id.* ¶ 10.

The '592 Patent does describe detailed abstract mathematical algorithms for supposedly cleaning data, which are set forth in page upon page of equations and formulae. *See, e.g.*, Ex. 1 ('592 Patent) at 45:4-48:55. It is undisputed that these algorithms are the core of what the patentees allegedly invented. Yet, none of these algorithms are claimed. At most, the claims recite a nebulous process of using "a

[1] The '592 Patent is attached as Exhibit 1 to the April 7, 2020 Declaration of Amanda K. Branch filed herewith. All citations to "Ex.__" refer to the April 7, 2020 Declaration of Amanda K. Branch filed herewith unless otherwise noted.

computer" to pick the "most likely" "hypothesis" corresponding to the fetal chromosome number. *See id.* at claim 1.

These steps are specified at a breathtaking level of generality and are reminiscent of descriptions of the scientific method that appears in basic science texts. The as-issued claims bear no resemblance to the particular statistical methods the patentees allegedly invented, and instead broadly encompass abstract statements of generic approaches to scientific inquiry that had long been the paradigm of medical diagnostics. As documented below, Natera's inventors, scientists, and experts repeatedly admitted that this is so. As such, the claims of the '592 Patent epitomize the type of overbroad and utterly generic technique that the Supreme Court and Federal Circuit have repeatedly held is ineligible for patenting under 35 U.S.C. § 101. Summary judgment on this basis is warranted.

While the hypothesis testing set forth in the claims is specified at an utterly generic and abstract level, the Court held in its Claim Construction Order that it is nonetheless directed to a data set that is acquired from only a single individual. *See* D.I. 81 at 12-15. The Illumina products, however, analyze data consisting of DNA from two individuals: a mother and a fetus. In Illumina's products, one never knows whether a particular piece of data arises from the mother or the fetus. The methods set forth in the '592 Patent—even when specified at the most general level—have nothing to do with Illumina's products, and Natera has failed to establish that multiple '592 Patent claim elements are present in Illumina's products. Summary judgment of non-infringement is thus also warranted.

II. SUMMARY JUDGMENT OF INVALIDITY OF THE '592 PATENT UNDER SECTION 101 SHOULD BE GRANTED

The Supreme Court has established a two-part framework for assessing patent eligibility under 35 U.S.C. § 101. *Alice Corp. Pty. Ltd. v. CLS Bank Int'l,* 573 U.S. 208, 217 (2014). First, the court determines whether the claims are "directed to" a law of nature, a natural phenomenon, or an abstract idea. *Id.* If so, the court proceeds to step two, to determine whether additional elements "transform the nature of the claim[s]" into patent eligible subject matter. *Id.* In particular, "simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable." *Mayo Collaborative Srvcs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 82 (2012). "Patent eligibility under 35 U.S.C. § 101 is a question

of law." *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1373 (Fed. Cir. 2016). As documented below, the '592 Patent is ineligible for patenting as a matter of law and summary judgment is warranted.

A. The '592 Patent Claims Are Directed To An Abstract Idea

The '592 Patent is directed to an abstract idea fundamental to all scientific inquiry: testing hypotheses.[2] Its only independent claim consists of two parts: a first, undisputedly conventional step that recites known sources of genetic material and data ("using a single nucleotide polymorphism (SNP) genotyping array or high throughput DNA sequencing to measure genetic material and produce genetic data"), and three steps that recite the abstract idea of creating hypotheses, determining their probabilities given data, and using the probabilities to determine which hypothesis is most likely:

> 1. An ex vivo method for determining a number of copies of a chromosome or chromosome segment of interest in the genome of an individual, the method comprising:
>
> using a single nucleotide polymorphism (SNP) genotyping array or high throughput DNA sequencing to measure genetic material and produce genetic data for some or all possible alleles at a plurality of at least 100 loci on the chromosome or chromosome segment of interest in the individual, wherein the genetic data is noisy due to a small amount of genetic material from the individual; and wherein the small amount of genetic material from the individual is from fifty or fewer of the individual's cells, 0.3 ng or less of the individual's DNA, extracellular DNA from the individual found in maternal blood, or combinations thereof;
>
> creating a set of one or more hypotheses specifying the number of copies of the chromosome or chromosome segment of interest in the genome of the individual;
>
> determining, on a computer, the probability of each of the hypotheses given the produced genetic data; and
>
> using the probabilities associated with each hypothesis to determine the most likely number of copies of the chromosome or chromosome segment of interest in the genome of the individual.

Ex. 1 ('592 Patent) at claim 1. Creating hypotheses, determining their probabilities, and using the probabilities to determine which is the most likely hypothesis is an unpatentable abstract idea fundamental to all scientific discovery.

In *Minitab, Inc. v. Engineroom, LLC,* a court held that claims directed to "[a] method of automatically applying hypothesis testing to at least one data set" are directed to an abstract idea that is

[2] In contrast, the '831 Patent's claim 1 is directed to a method of preparing a sequencing library and resembles claims directed to methods of preparing a DNA fraction that were recently held to be statutory subject matter in *Illumina Inc. v. Ariosa Diagnostics, Inc.*, Case No. 2019-1419, slip op. at 15 (Fed. Cir. March 17, 2020).

unpatentable under Section 101:

> The concept of hypothesis testing is one of the quintessential "basic tools of scientific ... work." *Benson,* 409 U.S. at 67. As Plaintiff states, it is a "fundamental analytic practice, which has been known, practiced in the field of statistics, and taught in statistics texts and classes, for many decades." (Doc. 83, p. 5). Therefore, we conclude that hypothesis testing is an abstract idea beyond the scope of § 101.

Minitab, Inc. v. Engineroom, LLC, 2015 WL 12517017, at *6 (M.D.Pa. 2015) (citing *Gottschalk v. Benson*, 409 U.S. 63 (1972)). The hypothesis-testing limitations in *Minitab* are strikingly similar to the hypothesis-testing limitations here, though the claims in *Minitab* included more detail. Among other limitations, the claims in *Minitab* recited

> constructing a null hypothesis statement and an alternative hypothesis statement . . . calculating the values of the test statistic, reference values, confidence bounds and p-values . . . comparing the value of the test statistic to one or more reference values, and . . . stating a conclusion based on the selected test and the indicated test criteria, the conclusion including whether to reject the null hypothesis or not reject the null hypothesis, and the basis for the conclusion.

Id. at *2. The Court held that "the claim recites describing the basic attributes of hypothesis testing" and that "[t]he addition of detailed steps alone will not transform an abstract idea into patent-eligible subject matter." *Id.* at *8. *Minitab* demonstrates that the '592 Patent's hypothesis testing limitations are directed to an unpatentable abstract idea.

Natera's own documents and witnesses confirm this. The presentation below, for instance, describes what Natera calls the "Paradigm of Medical Diagnostics." In this approach, one measures a parameter in a patient and checks to see whether that parameter is at an abnormally high end of the bell curve:

Ex. 10 (NAT-ILLUM0157722) at NAT-ILLUM0157725.

Natera's Senior VP of Research and Development, Dr. Sigurjonsson, specifically confirmed that this "Paradigm of Medical Diagnostics" is the basic concept of hypothesis testing and that it is within the scope of the claims:

Ex. 11 (Sigurjonsson Tr.) at 232:8-17. Dr. Sigurjonsson also admitted that Natera did not invent this approach. *Id.* at 239:9-23.

Natera's validity expert, Dr. Edwards, attempts to limit the hypothesis testing steps by reading Bayesian statistical concepts into claim 1:

Ex. 3 (Edwards Rpt.) ¶ 30. This cannot save the claims. In *Minitab,* the claims were significantly more limited, requiring (among other things) calculation of a "test statistic, reference values, confidence bounds and p-values." They are nevertheless unpatentably abstract. *Minitab,* 2015 WL 12517017, at *2, *6. The '592 Patent claims do not recite any calculations at all, much less specific p-values or test statistics.

The testimony and prior work of Natera's infringement expert, Dr. Parmigiani, demonstrate that even under Dr. Edwards' "Bayesian" interpretation, the claims are so abstract as to cover what Dr. Parmigiani has called "the prototypical example of probabilistic inference" in his prior-art textbook, "Modeling in Medical Decision Making - A Bayesian Approach" (Wiley, 2002). Ex. 6 (Parmigiani Book) at 7 ("Interpreting the result of a medical test in patient diagnosis is the prototypical example of probabilistic inference.").

Dr. Parmigiani's book explains that "[p]robabilistic inference deals with drawing conclusions about an individual who has been tested based on the result of the test, on what is known about the accuracy of the test, and on what is known more broadly about the medical condition that the test is attempting to reveal." *Id.* at 5. The book goes on to explain that the "positive predictive value" is a conditional probability that a person is diseased (the "diseased" hypothesis), given a positive diagnostic test result (the data):

> A natural way to translate this question in quantitative terms is to ask: What is the probability that the patient who tests positive is diseased? This is again a conditional probability, namely P(D+ | T+), and is called the positive predictive value…. Positive predictive value looks at a group of patients who walk out of the liver scan room with a positive result, and answers the question: How many of those really have liver disease? The latter is the relevant quantity to assist clinical decision making about patients who test positive.

Id. at 8.

In his infringement report, Dr. Parmigiani explains how the '592 Patent uses this "prototypical example of probabilistic inference":

[redacted]

[redacted]

Ex. 7 (Parmigiani Rpt) ¶ 54.

In deposition, Dr. Parmigiani admitted that the posterior probability for a person testing positive having the disease, p(H1|T), is just the positive predictive value for the test as described in his prior-art textbook. Ex. 8 (Parmigiani Tr.) at 32:5-12. Dr. Parmigiani also testified that the claim 1 limitation of "creating a set of one or more hypotheses specifying the number of copies of the chromosome or chromosome segment of interest in the genome of the individual" would be met by two hypotheses: H1 being the hypothesis that the person has Down syndrome (three copies of chromosome 21) and H0 being the hypothesis that the person does not. Ex. 8 (Parmigiani Tr.) at 12:1-13. Dr. Johnson, a named inventor, also confirmed that a hypothesis of the individual having an extra copy of a chromosome would be within the scope of the claims. Ex. 9 (Johnson Tr.) at 142:12-143:3. With these hypotheses, the other two hypothesis testing limitations ("determining, on a computer, the probability of each of the hypotheses given the produced genetic data; and using the probabilities associated with each hypothesis to determine the most likely number of copies of the chromosome or chromosome segment of interest in the genome of the individual") are met simply by determining the positive predictive value of the test and using that value to determine whether the person has Down Syndrome. This is nothing more than "[i]nterpreting the result of a medical test in patient diagnosis…the prototypical example of probabilistic inference." Ex. 6 (Parmigiani Book) at 7.

The '592 Patent specification contains many pages of equations and algorithms, but none of these equations or algorithms appear in the claims. Even Natera's validity expert Dr. Edwards opined that the [redacted] Ex. 3 (Edwards Rpt) ¶ 508. The Federal Circuit has routinely found such claims ineligible. *See, e.g.*, *SAP Am., Inc. v. InvestPic, LLC,* 898 F.3d 1161, 1167 (Fed. Cir. 2018) ("We have explained that claims focused on 'collecting information, analyzing it, and displaying certain results of the collection and analysis' are directed to an abstract idea….So, too, is 'analyzing information by mathematical algorithms, without

more.'"); *see also Electric Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1353 (Fed. Cir. 2016); *Internet Patents Corp. v. Active Network, Inc.*, 790 F.3d 1343, 1349 (Fed. Cir. 2015); *OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1363 (Fed. Cir. 2015); *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat'l Ass'n*, 776 F.3d 1343, 1347 (Fed. Cir. 2014); *Digitech Image Techs., LLC v. Elecs. for Imaging, Inc.*, 758 F.3d 1344, 1351 (Fed. Cir. 2014); *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1370 (Fed. Cir. 2011).

Therefore, the '592 Patent itself, as well as Natera's own documents, scientists, and experts, demonstrate that the hypothesis testing limitations of the '592 Patent are directed to the "paradigm of medical diagnosis," *i.e.*, "[i]nterpreting the result of a medical test in patient diagnosis…the prototypical example of probabilistic inference," and was not invented by Natera. This abstract idea is unpatentable subject matter.

The conventional first step of producing genetic data does not change this analysis. The first step of the Section 101 inquiry requires looking at the "focus" of the claims and their "character as a whole." The focus of the '592 Patent claims is the abstract concept of hypothesis testing (whether "Bayesian" or not), and the recitation of conventional subject matter (*e.g.*, SNP genotyping, DNA sequencing, etc.) does not save the claims. *See, e.g.*, *Mayo Collaborative Servs.*, 566 U.S. at 82 ("[S]imply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable."). The '592 Patent itself acknowledges that the step of producing genetic data in claim 1 is conventional: "Genetic data for the target individual is acquired and amplified using known methods...." Ex. 1 ('592 Patent) at Abstract. The '592 Patent's Claim 19 reinforces this point and demonstrates the generality of claim 1 by reciting a laundry list of conventional genetic techniques that may be used to perform claim 1.

Natera has also acknowledged as much in briefing and testimony. *See, e.g.*, D.I. 72 at 8 ("At the time of the invention, typical SNP genotyping techniques analyzed locations in an individual's genome at sites where variations were known to occur"; also, citing Ex. 1 ('592 Patent) at 5:13–33, 8:11–23 describing conventional DNA sequencing methods). And in response to a question about what was new in claim 1, '592 Patent first-named inventor and Natera founder Dr. Rabinowitz admitted that [redacted] and

instead [redacted] Ex. 2 (Rabinowitz Tr.) at 270:3-16.

Similarly, Dr. Edwards opined the [redacted] and that the '592 Patent [redacted] Ex. 3 (Edwards Rpt) ¶¶ 507, 512. Likewise, Natera's primary infringement expert Dr. Eshoo opined that the [redacted] Ex. 4 (Eshoo Rpt) ¶ 75; *see also* Ex. 5 (Eshoo Tr.) at 82:14-22; *id.* at 83:9-86:24. Dr. Eshoo further confirmed at deposition that [redacted] was the novel part of the invention. *Id.* at 86:19-24.

Claiming the concept of hypothesis testing in the context of chromosome copy number also does not change the abstract character of the claim as a whole. *SAP Am., Inc.,* 898 F.3d at 1168 ("[A]s many cases make clear, even if a process of collecting and analyzing information is 'limited to particular content' or a particular 'source,' that limitation does not make the collection and analysis other than abstract.").

There is thus no dispute that the focus of the '592 Patent's claim 1 is hypothesis testing and that the remainder of the claim is directed to conventional subject matter. As a result, claim 1 is directed to an unpatentable abstract idea.

B. Nothing In The Claims Provides An "Inventive Concept"

1. Claim 1

Step two of the *Alice* analysis requires a search for an "inventive concept" to determine whether the patent amounts to "significantly more than a patent upon the ineligible concept itself." *Alice,* 573 U.S. at 218. Nothing in claim 1 provides an "inventive concept." The elements of claim 1 were well-known and commonly used techniques, which are not sufficient to transform the nature of the claims. *Id.* at 222 ("Simply appending conventional steps, specified at a high level of generality, [is] not enough to supply an inventive concept.").

There can be no meaningful dispute that the concept of hypothesis testing was well known in the art. For example, Dr. Sigurjonsson confirmed that the [redacted]

[redacted] Ex. 11 (Sigurjonsson Tr.) at 239:9-23. And named inventor Dr. Johnson likewise testified that the last three steps of Claim 1 (regarding the hypothesis) are not inventive for the same reasons. Ex. 9 (Johnson Tr.) at 146:12-147:7. Even under Natera's "Bayesian" interpretation, Natera's documents and testimony demonstrate that the hypothesis testing steps were so well known that they cover the "paradigm of medical diagnosis," *i.e.*, "[i]nterpreting the result of a medical test in patient diagnosis…the prototypical example of probabilistic inference." *See* Ex. 6 (Parmigiani Book) at 7. This evidence demonstrates that the hypothesis testing steps do not provide an inventive concept, but rather were well-known in the art long before the purported invention of the '592 Patent.

The claimed hypothesis testing steps are also too abstract and devoid of detail to provide inventive concept. Despite pages of equations and formulae in the specification, the claims recite nothing concerning ***how*** to determine the "probability of each of the hypotheses" other than that it be done "on a computer." *See* Ex. 11 (Sigurjonsson Tr.) at 224:10-17 (confirming there is not [redacted] for how to determine the probability); Ex. 9 (Johnson Tr.) at 149:13-150:2 (confirming that there was not any algorithmic limitation for determining probability other than "on a computer"). Dr. Sigurjonsson testified that the step of "creating a set of one or more hypotheses…" could be as simple as writing one down. Ex. 11 (Sigurjonsson Tr.) at 222:20-25. Even Natera's expert Dr. Edwards points to the specification to provide the details of the "mathematical algorithms" supposedly used by the claims, rather the claims themselves. Ex. 3 (Edwards Rpt) ¶ 515 [redacted] Similarly, Natera's senior director of scientific communications and clinical research, Dr. Demko, testified that the "determining" step did not require any particular algorithm. Ex. 12 (Demko Tr.) at 124:2-7 [redacted] And while Natera contends that the objective of the '592 Patent was to address noise in genetic data, named inventor Dr. Banjevic testified that the '592 Patent was not limited to addressing any particular kind of noise, and Dr. Sigurjonsson testified that noise is present any time genetic data is processed or measured. Ex. 13 (Banjevic Tr.) at 157:14-25; Ex. 11 (Sigurjonsson Tr.) at 196:23-197:7. In any event, the abstract idea of hypothesis testing cannot provide an inventive concept in and of itself. *Berkheimer v. HP Inc.*, 890 F.3d 1369, 1374 (Fed. Cir.

2018) ("It is clear from *Mayo* that the 'inventive concept' cannot be the abstract idea itself").

The remaining portions of this step of claim 1 also fail to supply an inventive concept. It recites "using a single nucleotide polymorphism (SNP) genotyping array or high throughput DNA sequencing to measure genetic material and produce genetic data" from a "small amount of genetic material." This is nothing more than using known techniques and commercially available equipment to acquire data from a small amount of DNA. This is confirmed by claim 19, which depends from claim 1, and recites a laundry list of conventional techniques that can be used to carry out the accused method. *See* Ex. 1 ('592 Patent) at claim 19. If step 1 of claim 1 could be provided by a wide variety of commonplace techniques, it cannot be inventive.

The '592 Patent specification also admits that many techniques for obtaining genetic data from a small amount of genetic material were well known in the art. *See, e.g.,* Ex. 1 ('592 Patent) at 4:4-16, 4:20-23, 4:45-50, 5:1-7, 5:12-13, 5:34-37. For example, the '592 Patent admits "[g]enetic data for the target individual is acquired and amplified using known methods" (*id.* at Abstract) and that "[m]any techniques exist which provide genotyping data." *Id.* at 4:20. Similarly, U.S. Patent Prov. App. No. 60/739,882, to which the '592 Patent claims priority, states that, "[t]he current invention is independent of the measurement technique used to gather the genomic data." Ex. 14 (U.S. Patent Prov. App. No. 60/739,882) at NAT-ILLUM0007218. The '592 Patent specification also acknowledges that, "[c]urrent techniques are able to isolate small quantities of fetal cells from the mother's blood," then describes "[t]he most effective technique" as well as "other techniques." Ex. 1 ('592 Patent) at 1:60-2:1. Similarly, the specification admits that "[m]any techniques exist for isolating single cells." *Id.* at 2:21.

Natera's witnesses confirmed that all of the elements of the introductory step were routine, conventional, and well known. For example, named inventor Dr. Rabinowitz acknowledged that [redacted] Ex. 2 (Rabinowitz Tr.) at 271:16-18. Dr. Rabinowitz likewise testified that [redacted] *Id.* at 269:21-270:16. Similarly, named inventor Dr. Johnson admitted that measuring SNPs using commercially available sequencing platforms was routine and conventional. Ex. 9 (Johnson Tr.) at 62:18- 63:14. And Natera's expert Dr. Eshoo testified that SNP genotyping arrays and high throughput sequencing were not things that Natera

invented. Ex. 5 (Eshoo Tr.) at 180:20-181:2.

Dr. Eshoo also confirmed that obtaining small amounts of fetal DNA was known in the art. Dr. Eshoo agreed that [redacted] *Id.* at 182:10-12. Dr. Eshoo noted that the "first papers" relating to NIPT using cell free DNA dated [redacted] *Id.* at 74:3-8. Dr. Eshoo also testified that there were no new techniques for how to obtain genetic data from a small amount of genetic material described in the patent. *Id.* at 184:13-16 (agreeing these "were previously known methods"); *see also id.* at 181:14-182:8, 185:7-10.

The Federal Circuit has repeatedly held that conventional laboratory techniques cannot supply an inventive concept to an otherwise unpatentable idea. *Roche Molecular Sys. v. Cepheid*, 905 F.3d 1363, 1373 (Fed. Cir. 2018) (finding patent-ineligible "claims [to] a method of detection based on a natural phenomenon and employs only conventional, well-known laboratory techniques,"); *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig. v. Ambry Genetics Corp.* ("*In re BRCA*"), 774 F.3d 755, 764 (Fed. Cir. 2014) (finding "non-patent-ineligible elements of claims 7 and 8" which were "were the well-understood, routine, and conventional techniques that a scientist would have thought of" did not "add 'enough' to make the claims as a whole patent-eligible."). Applying the basic scientific or diagnostic building blocks of hypothesis testing to genetic data from conventional sources obtained using well-known and conventional methods does not render the method patentable.

There is no genuine dispute that these laboratory steps were routine and conventional. Natera's relevant expert did not opine that the particular methodologies used to obtain the genetic material or genetic data were novel or inventive. Instead, Natera contends that the inventive concept is the application of algorithms in the specification to these well-known, routine and conventional techniques. *See, e.g.,* Ex. 3 (Edwards Rpt) ¶ 515 [redacted] But these algorithms do not appear in the claims. And claims directed to abstract ideas are ineligible for patent protection when, apart from the abstract idea itself, "they involve well-understood, routine, conventional activity previously engaged in by researchers in the field." *Mayo*, 566 U.S. at 73. The Federal Circuit's decision in *In re BRCA* is instructive. There, the court concluded that claims directed to the abstract idea of comparing various sequences, were not

saved by the recitation of claim limitations that did "nothing more than spell out what practitioners already knew—how to compare gene sequences using routine, ordinary techniques," such as "hybridizing," "detecting," "amplification," and "sequencing." 774 F.3d at 764-65. The same is true here.

Claim 1 also recites that "the genetic data is noisy due to a small amount of genetic material from the individual." Nothing about the presence of noise in data, however, is novel or inventive. The '592 Patent itself even asserts that measuring small amounts of genetic material results in data that is "inherently noisy." Ex. 1 ('592 Patent) at 8:19-23 ("Given the inherently noisy nature of the measured genetic data in cases where limited genetic material is used for genotyping, there is a great need for a method which can increase the fidelity of, or clean, the primary data."). Natera's expert Dr. Edwards also identified "noisy data" as a "prior art problem." Ex. 3 (Edwards Rpt) ¶ 507 [redacted]. And Dr. Sigurjonsson testified that there would be noise whenever genetic data is processed or measured. Ex. 11 (Sigurjonsson Tr.) at 196:23-197:7.

Claim 1 also requires determining probabilities "on a computer."[3] The Federal Circuit has held that simply performing an abstract idea on a computer cannot transform the idea into patentable subject matter. *Alice*, 537 U.S. at 223 ("[i]f a patent's recitation of a computer amounts to a mere instruction to 'implement' an abstract idea 'on . . . a computer,' that addition cannot impart patent eligibility."). Claim 1 is not directed to any particular way of determining probabilities on a computer. It therefore amounts to a mere instruction to implement the abstract idea on a computer and cannot transform the claim into patentable subject matter.

Because the focus of claim 1 is an abstract idea and the claim is otherwise directed to elements that are unquestionably routine and conventional, the Court should find that it is directed to patent-ineligible subject matter under *Alice* step 2.

[3] Natera added "on a computer" to a very similar claim in Natera's U.S. Patent No. 8,532,930 ("'930 Patent") to overcome a rejection under Section 101. Ex. 22 (Nov. 18, 2010 Amendment) at 15, 25-26. The '592 Patent is a continuation of the '930 Patent. The examiner of the '592 Patent rejected the claims as obvious over this claim of the '930 Patent and Natera overcame the rejection with a terminal disclaimer. Ex 23 (Dec. 19, 2013 Amendment) at 21.

2. Dependent Claims

The other asserted claims—claims 2-4, 5, 7-9, 15, 17, or 19-27, all of which depend directly or indirectly from claim 1—add nothing beyond routine, conventional, and well-understood techniques, and they too are therefore insufficient to transform the nature of the abstract idea into patentable subject matter.

Claims 2, 3, and 4 require that the "small amount of genetic material" be 20 or fewer cells, one cell, or less than .3 ng.[4] Obtaining DNA from small amounts of genetic material was well-known. The specification admits that "[m]any techniques exist for isolating single cells" (Ex. 1 ('592 Patent) at 2:21) and that "[c]urrent techniques are able to isolate small quantities of fetal cells from the mother's blood." *Id.* at 1:60-61. Named inventor Dr. Johnson also confirmed techniques for isolating and collecting DNA from 50 cells were known (Ex. 9 (Johnson Tr.) at 136:16-20), as was collecting .3 nanograms or less of an individual's DNA. *Id.* at 137:2-11. Dr. Eshoo also confirmed such techniques were known in the art. *See* Ex. 5 (Eshoo Tr.) at 184:13-16 (agreeing these [redacted]); *see also* Declaration of Dr. Henry M. Furneaux In Support of Illumina, Inc.'s Motion for Summary Judgment ("Furneaux Decl."), Ex. A (Furneaux Rpt) ¶ 614-615.

Claims 5, 17, and 20 require certain sources for the genetic material, including extracellular DNA in maternal blood, a maternal blood sample, or one of a variety of genetic material "known to have originated from the individual" such as embryonic cells. These sources were known and commonly used in the field. The '592 Patent admits that it "has recently been discovered that cell-free fetal DNA and intact fetal cells can enter maternal blood circulation" (Ex. 1 ('592 Patent) at 1:50-51) and acknowledges that isolation techniques were known. *Id.* at 1:60-2:1. In fact, the presence of fetal DNA in maternal blood was discovered long before the purported invention of the '592 Patent, as described in a 1997 article. *See* Ex. 15 (Lo YM et. al., Presence of fetal DNA in maternal plasma and serum. Lancet. 199 7 Aug 16; 350 (9076):485-7); *see also* Ex. 9 (Johnson Tr.) at 137:13-22 (admitting collection of DNA from maternal blood was known). The '592 Patent also describes "[i]solation of single cells from human embryos" as "routine." Ex. 1 ('592 Patent) at 2:32-34.

[4] The specification notes that .3 ng is equivalent to approximately 50 cells. Ex. 1 ('592 Patent) at 29:53-54.

Other dependent claims add nothing more than known statistical concepts—claim 7 merely adds a requirement of "measurement bias," claim 8 a requirement of "incorrect measurements," claims 24-26 a step of "normalizing the genetic data." However, "[a]dding one abstract idea (math) to another abstract idea…does not render the claim non-abstract." *RecogniCorp, LLC v. Nintendo Co.*, 855 F.3d 1322, 1327 (Fed. Cir. 2017). Similarly, claim 9 requires computation of a "confidence," which the patent defines as nothing more than a "statistical likelihood," while claim 27 requires determining a probability without a reference sample. However, "the addition of a mathematical equation that simply changes the data into other forms of data cannot save [the claim]." *Id.* at 1328. These basic statistical concepts were well-known and routine. *See, e.g.*, Ex. 9 (Johnson Tr.) at 79:12-21 (admitting [redacted] in 2006); Ex. 5 (Eshoo Tr.) at 189:23-190:23 (explaining that running normalization for arrays was a routine process in Dr. Eshoo's lab in the early 2000 timeframe); Furneaux Decl., Ex. A at ¶ 621. Such well-known statistical concepts do not transform the nature of the claims. *PerkinElmer, Inc. v. Intema Ltd.*, 496 F. App'x 65, 71 (Fed. Cir. 2012) (nonprecedential) ("The statistical information mentioned in this step is insufficient to make the claim patent-eligible because it is well-understood, conventional information.").

Claim 15 adds the mental step of clinical decision making: "wherein the determination of the number of copies of the chromosome or chromosome segment of interest is used to make a clinical decision about the individual." This "clinical decision" step does change the abstract nature of the claim. *See, e.g., Ariosa Diagnostics Inc. v. Sequenom, Inc*, 788 F.3d 1371, 1378 (Fed. Cir. 2015) (performing a prenatal diagnosis is a mental process); *see also Genetic Techs.*, 818 F.3d at 1379 (finding "the addition of this mental process step to the routine and conventional physical activity of amplification and analysis" did not transform claims).

Claim 19 recites a laundry list of routine, conventional, and well-understood techniques for amplifying and sequencing the genetic material. As the '592 Patent specification acknowledges, these methods were conventional. *See* Ex. 1 ('592 Patent) at Abstract. Named inventor Dr. Johnson also admitted using commercially available platforms was routine in the field. Ex. 9 (Johnson Tr.) at 62:18-63:14. There can be no question that amplification and PCR were well-understood, routine, conventional activities engaged in by those in the field long before the priority date of the '592 Patent.

See Ariosa, 788 F.3d at 1377; *see also* Furneaux Decl, Ex. A ¶ 623-624. And, indeed, Dr. Eshoo agreed. Ex. 5 (Eshoo Tr.) at 191:13-24 [redacted] process for amplification known before the priority date). Dr. Eshoo also confirmed that [redacted] *Id.* at 191:25-192:2.

Claims 21 and 22 require selection of a chromosome or abnormality of interest from a group of known chromosomes (for example, chromosome 21 or the Y chromosome) or known abnormalities (such as Down syndrome). Claim 23 requires identifying the probability that the individual possesses a particular abnormality. The '592 Patent acknowledges that these chromosomal abnormalities were known in the art. *See* Ex. 1 ('592 Patent) at 7:7-9 ("Detection of chromosomal abnormalities can identify individuals or embryos with conditions such as Down syndrome, Klinefelters syndrome, and Turner syndrome, among others"). These conditions are also unpatentable natural phenomena. These claims do not add any steps to the method and, instead, simply narrow the scope from a "chromosome of interest" to a particular disorder or the chromosome that causes it. It is well-established that "[a] specific type of a natural phenomenon is still a natural phenomenon and, thus, is not patentable." *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 19 F. Supp.3d 938, 950 n.5 (N.D. Cal. 2013) (finding an additional limitation "that the cffDNA is from a Y chromosome" did not render claim patent eligible).

Because the asserted dependent claims do not change the abstract nature of their parent claim 1, and do not add anything that could otherwise transform the claim into patentable subject matter, the Court should find all of the asserted claims unpatentable under Section 101.

III. SUMMARY JUDGMENT OF NONINFRINGEMENT OF THE '592 PATENT SHOULD BE GRANTED

In addition to being ineligible under Section 101, the '592 Patent is also not infringed. The '592 Patent is directed to a prior-art approach based on measuring fetal and maternal DNA separately. The Illumina Accused NIPT Products,[5] however, use a modern approach developed at both Stanford University and the Chinese University of Hong Kong that measures fetal and maternal DNA together.

[5] The Illumina Accused NIPT Products are the: (i) Verifi, (ii) Verifi Plus, and (iii) VeriSeq NIPT products. The fourth Illumina Accused Product is VeriSeq PGS, which does not utilize a maternal blood sample and is a different category of product.

As the Court noted in its Claim Construction Order, the '592 Patent does not encompass this approach, which was not even invented until long after the alleged priority date of the '592 Patent. *See* D.I. 81 at 12-15. Because the '592 Patent is directed to a method that has nothing to do with the approach used in Illumina's products and Natera fails to establish that multiple claim elements are present, summary judgment of non-infringement is warranted.

A. The Illumina Accused NIPT Products Do Not Measure DNA "From Only The Individual"

1. Natera Cannot Prove Infringement Given The Court's Construction

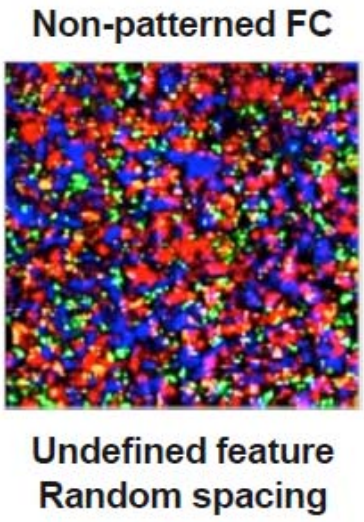
In its Claim Construction Order, the Court construed the term "at least 100 loci on the chromosome or chromosome segment of interest in the individual" to mean: "at least 100 loci on the chromosome or chromosome segment of interest from ***only*** the individual." D.I. 81 at 15.[6] As the Court explained:

- "both the claims and specification demonstrate that the claimed method is directed to the analysis of samples containing the DNA of only one individual." *Id.*
- the "specification also repeatedly states that fetal genetic material (e.g. 'cell-free fetal DNA') is isolated from the maternal blood prior to analysis. The specification makes clear that the target of analysis is fetal DNA. Accordingly, ***fetal and maternal DNA are measured separately***." *Id.*

The Illumina Accused NIPT Products do not remotely match this description.

In the Illumina Accused NIPT Products, a blood sample is taken from a pregnant woman. The blood sample contains millions of tiny fragments of ***both*** fetal and maternal DNA. The millions of fetal and maternal DNA fragments are then randomly dispersed across the surface of a "flow cell," which is the component of an Illumina high-throughput sequencer (also known as a "massively parallel" or "next-generation" sequencer) where the sequencing takes place. At each random location where a DNA fragment attaches to the flow cell, the sequencer makes copies of the DNA fragment, yielding a "cluster" of each DNA fragment. The image below shows a representative Illumina flow cell; each colored spot represents a "cluster:"

[6] Emphasis supplied unless otherwise noted.



Ex. 21 (Illumina Presentation: "Exploring Illumina's Newest Sequencing Solutions") at 7.

In the Illumina Accused NIPT Products, there is no way of knowing whether any particular cluster arises from a fetal DNA fragment or maternal DNA fragment. The DNA fragments from both the mother and fetus are then sequenced together on the Illumina flow cell and then analyzed as a collective without any ability to distinguish the fetal and maternal DNA. *See, e.g.*, Ex. 16 (ILMN_NAT00021364) ("Whole genome sequencing using massively parallel sequencing (MPS) technology is performed on the total cfDNA isolated from maternal plasma. Reported results are based on analysis of the total cfDNA").

This workflow does not satisfy the claims of the '592 Patent as construed by the Court. The samples do not contain the "DNA of only one individual," as specified in the Court's claim construction order. D.I. 81 at 15. If one were truly measuring fetal DNA "separately" from maternal DNA, as specified in the Court's claim construction order, one would know whether a particular piece of sequence information arises from the fetus or the mother. Yet, it is undisputed that in Illumina's products one never knows this information throughout the entire sequencing and analysis process. *See* Furneaux Decl., Ex. B (Furneaux Rpt) ¶ 85.[7] Rather, the fetal and maternal DNA is naturally mixed and applied to the sequencer as a mixture such that it is impossible to ever determine at this stage whether any given piece of sequence information arose from the fetus or mother. It thus cannot be that the "fetal and maternal DNA are measured separately," as specified in the claim construction order. *See* D.I. 81 at 15.

[7] Natera's expert Dr. Eshoo confirmed that he did not opine on this point. *See* Ex. 5 (Eshoo Tr.) at 112:17-21. Therefore, this fact is undisputed.

Importantly, Natera has asserted in a co-pending IPR that the "produced genetic data" from which "hypotheses" are generated in the claim refers to the data from the "individual" that is measured. *See* Ex. 20 (IPR POR) at 26 ("'[T]he produced genetic data' refers, in claim 1, to the claimed 'genetic data for some or all possible alleles at a plurality of at least 100 loci on the chromosome or chromosome segment of interest in the individual' which is 'produce[d]' in step 1[i]."). Because the data that is analyzed in Illumina's products is undisputedly from multiple individuals and because there is no knowledge regarding whether an individual DNA fragment arises from the fetus or mother, by Natera's own admission Illumina's products do not measure data from "only the individual," as the claims require.

Consistent with the foregoing, Natera's primary infringement expert, Dr. Eshoo, confirmed that the Illumina Accused NIPT Products use a maternal blood sample comprised of both maternal and fetal DNA. *See* Ex. 5 (Eshoo Tr.) at 108:7-13, 109:12-14. Dr. Eshoo admitted that during the sequencing process the maternal and fetal DNA would be [redacted] that is used in the Illumina sequencer. *Id.* at 121:17-24. He further agreed that this random distribution would be such that [redacted] and testified further that there would be [redacted] *Id.* at 122:2-5, 122:13-14. Confirming that there would not be any semblance of order to the DNA, Dr. Eshoo agreed that [redacted] *Id.* at 122:6-11.

Based on the foregoing, there can be no genuine dispute that Illumina's products do not satisfy the '592 Patent claims as construed by the Court. They do not involve the analysis of samples "containing the DNA of only one individual." D.I. 81 at 15. The fetal genetic material is not "isolated from the maternal blood prior to analysis." *Id.* In Illumina's products, one will never know whether a particular DNA fragment arises from the fetus or mother. Fetal and maternal DNA thus cannot possibly be deemed "measured separately," (*id.*), but are instead measured together. Because one does not generate data from only the "individual," as the claims require, summary judgment of non-infringement is warranted.

2. Natera's Post-Claim Construction Infringement Theory Is Without Merit

Having lost decisively at claim construction, Natera now contends that fetal and maternal DNA is actually measured separately through a meritless theory that is directly at odds not only with Dr. Eshoo's numerous admissions regarding the operation of the Illumina sequencer, but also the admissions of Natera's other experts and scientists.

Natera asserts that in the Illumina Accused NIPT Products millions of DNA fragments are dispersed randomly across the surface of a "flow cell" such that every fragment is ideally some tiny distance away from every other DNA fragment. *See, e.g.*, Ex. 4 (Eshoo Rpt) ¶ 128. Based on this spatial dispersion of DNA fragments, Natera contends that ***every*** individual DNA fragment is measured separately from every other individual DNA fragment. *Id.* According to Natera, since every fragment is allegedly measured individually, any arbitrarily selected ***group*** of DNA fragments must be measured separately from any other arbitrarily measured group. To argue infringement, Natera contends that it can arbitrarily point to the group of fetal DNA fragments on the flow cell (even though nobody actually knows which DNA fragments correspond to the fetus) and assert that they are measured separately from the maternal DNA (even though after sequencing is completed nobody knows which data actually corresponds to the fetus).

Natera's theory is too cute by half and is contrary to the Court's claim construction order and the understanding of the skilled artisan. Most significant here is the admission of Natera's expert Dr. Metzker whom Dr. Eshoo characterized as an "authority" in the high throughput sequencing field. Ex. 5 (Eshoo Tr.) at 93:8-14. Dr. Metzker opined on the use of "indexes" to tag the DNA fragments from multiple samples so they can all be placed on the sequencer at the same time. Even though the fragments from multiple samples are randomly dispersed on the flow cell and mixed amongst one another, the "index" can be used after the sequence data is obtained to determine which sample each DNA fragment came from. Dr. Metzker explained that in this process the samples are "sequenced ***together*** in a single reaction":

> Next-generation sequencers could sequence millions of DNA molecules in a single run and thereby enabled DNA sequencing of different individuals ***at the same time***…The advantage of 'indexing' was that DNA from different individuals could be pooled and ***sequenced together in a single reaction***.

Ex. 17 (Metzker Rpt) ¶ 52; *see also* Ex. 5 (Eshoo Tr.) at 98:1-16 (confirming that Illumina's sequencers are "next generation" sequencers).

If there were any merit to Natera's theory that when one simultaneously places DNA from multiple individuals on an Illumina sequencer they are actually measured "separately," as required by the Court's claim construction order, Dr. Metzker would never have described this process as sequencing multiple samples "***together*** in a single reaction." As Dr. Metzker's opinion makes clear, those of skill in the art understand that when a sample containing the DNA of multiple individuals is placed on a next-generation sequencer, the DNA from those individuals is measured "together," not "separately," as specified in the Court's claim construction order. *See* D.I. 81 at 15.

Confirming this to be the case, two principle Natera scientists, Dr. Sigurjonsson (Senior V.P. of R&D) and Dr. Zimmerman (V.P. of R&D), agreed that in the method used in Illumina's NIPT products the maternal and fetal DNA are measured together. *See* Ex. 11 (Sigurjonsson Tr.) at 123:12-19 (Q. [redacted]); Ex. 18 (Zimmerman Tr.) at 137:14-138:13 (Q. [redacted] (objection omitted)).

Natera's theory that when both fetal and maternal DNA are randomly dispersed on the flow cell and sequenced simultaneously they are actually measured separately would, if adopted, effectively read the term "individual" out of the claims and render the Court's construction moot. As Natera's expert Dr. Eshoo confirmed, ***every*** "high throughput sequencing platform" involves dispersing individual DNA fragments:

[redacted]

Ex. 5 (Eshoo Tr.) at 119:1-5. If Natera's infringement theory were adopted, it would be impossible to sequence multiple samples together using high throughput sequencing. Indeed, Dr. Eshoo testified that he had no idea how one could measure DNA from multiple samples together using high throughput

sequencing:

See Ex. 5 (Eshoo Tr.) at 119:6-17 (objections omitted). Under Natera's theory, separate measurement of maternal and fetal DNA is inherent in "high throughput sequencing." Yet, as the Court recognized in its claim construction order—over Natera's strenuous objection[8]—the claims include a separate and distinct requirement from the use of "high throughput sequencing" that one generate genetic data from the "only the individual." Natera's theory, which has the effect of reading the term "individual" out of the claims and rendering the Court's construction moot, cannot be right.

Separate measurement of fetal and maternal DNA is not inherent in "high throughput sequencing." As the evidence set forth above establishes, when a mixture of fetal and maternal DNA is sequenced on a high throughput sequencer without any isolation of fetal DNA and without any knowledge of whether a fragment arises from the fetus or mother, those of skill in the art understand that the fetal and maternal DNA are measured together, not separately. Natera has not—and cannot—show that the Illumina Accused NIPT Products produce genetic data "from only the individual" by measuring the maternal and fetal DNA separately and, therefore, summary judgment of non-infringement is warranted.

B. The Illumina Accused Products Do Not Produce "Genetic Data For Some Or All Possible *Alleles* At A Plurality Of At Least 100 Loci"

The claims of the '592 Patent all require the generation of "genetic data for some or all possible alleles at a plurality of at least 100 loci on the chromosome or chromosome segment of interest in the individual." This claim element refers separately to both "loci" and "alleles." These two distinct terms encompass different concepts. *See, e.g.*, Ex. 5 (Eshoo Tr.) at 123:12-15, 126:1-5, 126:16-21, 129:12-17. In particular, it is undisputed that "alleles" are genomic positions that vary from individual to

[8] *See, e.g.*, D.I. 75 at 12-15.

individual, a point the Court noted in its Claim Construction Order. D.I. 81 at 4 n.2. Every named inventor confirmed this. *See, e.g.*, Ex. 9 (Johnson Tr.) at 108:17-24; Ex. 13 (Banjevic Tr.) at 220:5-14, 218:16-25; Ex. 12 (Demko Tr.) at 101:18-102:5; Ex. 2 (Rabinowitz Tr.) at 247:4-8. Likewise, Natera's expert on infringement, Dr. Eshoo, confirmed that "alleles" and "loci" are "really different terms:"

Ex. 5 (Eshoo Tr.) at 89:4-9. This, in requiring the generation of genetic data for "alleles," the claims expressly require genetic data for particular loci constituting points of variation—not just any random loci on the genome. This distinction matters because only a very small portion of the genome—less than 1%—varies from person to person. *See, e.g.*, Furneaux Decl., Ex. B (Furneaux Rpt) ¶ 100.

During claim construction, the Court construed "genetic data for some or all possible alleles" to mean "genetic data for some or all possible base pairs at a given locus." D.I. 81 at 12. This construction takes into account the defining feature of an allele—that it is a point of variation. Indeed, the Court explained that an "allele is particular variation of a gene." *Id.* at 4 n.2. The Court also observed that "[e]xamining a number of loci in sequence allows geneticists to determine what variant of a gene, *i.e.* which allele, an individual has in their genome." *Id.* at 4 n.3. The Court's construction, in requiring data for "possible base pairs" means requiring data for places where the base pairs are not necessarily the same. In the context of the claims, then, genetic data must be generated for alleles (points of variation) rather than just any loci (points that do not necessarily vary).

Natera has not shown the Illumina Accused Products[9] produce genetic data for "alleles." Neither of Natera's two experts on infringement provided any evidence whatsoever that the Illumina Accused Products generate genetic data for points of variation in the genome (*i.e.*, "alleles"). Natera's first expert, Dr. Parmigiani, "deferred" to Dr. Eshoo on this claim element and presented no opinions or analysis. *See* Ex. 7 (Parmigiani Rpt) ¶ 102. As to Dr. Eshoo, the only mention of the "alleles" in his report is in restating the claim limitation. Dr. Eshoo does not mention or apply "genetic data for some or all possible

[9] The "Illumina Accused Products" are the: (i) Verifi, (ii) Verifi Plus, (iii) VeriSeq NIPT, and (iv) VeriSeq PGS products—all of the Illumina products accused in this matter.

base pairs at a given locus" anywhere else in his report. *See* Ex. 4 (Eshoo Rpt) ¶¶ 99-132.

At most, Dr. Eshoo opines that the Illumina Accused Products sequence at least 100 loci of a chromosome. *See id.* But, as set forth above, the claims do not merely require loci—they require alleles, or points of variation. While Dr. Eshoo agrees that alleles are not generic loci, but rather points of variation, he did not apply the terms in this manner. In fact, Dr. Eshoo testified that he did not even understand how the Court's construction of "genetic data for some or all possible alleles" reflects the understanding of "alleles" to the skilled artisan:

[redacted]

Ex. 5 (Eshoo Tr.) at 160:19-25 (objection omitted). Instead of identifying any alleles or points of variation, Dr. Eshoo merely identifies loci and contends this is sufficient for infringement. Neither Dr. Eshoo nor Dr. Parmigiani did any calculations or provided any data to establish that the Illumina products generate genetic data for even one allele, much less 100 alleles, as the claim requires.

It is unsurprising that there was a total failure of proof on this issue. As Dr. Sung Kim, Illumina's Associate Director of Bioinformatics, explained, the Accused Products have depth of coverage at approximately 0.1 to 0.2X. Ex. 19 (Kim Tr.) at 41:24-42:7. [redacted] *Id.* at 40:16-21; *see also* Ex. 4 (Eshoo Rpt) ¶ 144 [redacted] In light of this shallow depth of coverage, Natera cannot establish that the Illumina Accused Products generate data for any alleles, as confirmed by the unrebutted testimony of Illumina's expert. *See* Furneaux Decl., Ex. B (Furneaux Rpt) ¶¶ 103-18. Because there is no dispute that that the Illumina products do not generate the data that is required by the claims, summary judgment of non-infringement is warranted.

C. Summary Judgment Of Non-Infringement Of The '592 Patent By VeriSeq PGS Is Warranted Because Natera Has Presented No Evidence That The Genetic Data Is "Noisy"

Claim 1 of the '592 Patent recites "wherein the genetic data is noisy due to a small amount of genetic material from the individual." Natera has presented no evidence that the VeriSeq PGS product

meets this limitation and summary judgment of non-infringement is warranted.

Although Natera proffered opinions from two experts regarding infringement of the'592 Patent, only one, Dr. Eshoo, purported to address this element.[10] The only reference to VeriSeq PGS in the entirety of Dr. Eshoo's analysis of this claim element, however, is a single sentence: [redacted] Ex. 4 (Eshoo Rpt) ¶ 134. Dr. Eshoo presents no explanation or evidence regarding whether the genetic data is "noisy," as the claim element requires.

Dr. Eshoo acknowledges that the '592 Patent defines noisy genetic data as: [redacted] Ex. 4 (Eshoo Rpt) ¶ 139. But he does not address any of these sources of noise—or any other sources for that matter—in connection with the VeriSeq PGS product. Instead, when asked about the basis for his opinion regarding noise in the VeriSeq PGS product, Dr. Eshoo could provide no support for any conclusion that the genetic data is "noisy" in VeriSeq PGS:

[redacted]

Ex. 5 (Eshoo Tr.) at 200:12-19.

Summary judgment of noninfringement "is appropriate where the patent owner's proof is deficient in meeting an essential part of the legal standard for infringement, because such failure will render all other facts immaterial." *TechSearch, L.L.C. v. Intel Corp.*, 286 F.3d 1360, 1369 (Fed. Cir. 2002) (citing *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534 (Fed. Cir. 1991)). Because Natera's proof of infringement of this product is wholly deficient, summary judgment is appropriate and should be granted. *Id.*

IV. CONCLUSION

For the foregoing reasons, Illumina respectfully requests that this Motion be granted.

[10] Dr. Parmigiani, Natera's purported statistics expert, deferred to Dr. Eshoo for this limitation of claim 1. *See* Ex. 7 (Parmigiani Rpt) ¶162.

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Respectfully submitted,

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